

U.S. Patent Application Serial No. 10/566,085
Amendment filed August 7, 2009
Reply to OA dated May 7, 2009

REMARKS

Claims 1-20 are pending in this application. Claims 1, 2, 5, 9-14, 16, 17, 19 and 20 are canceled without prejudice or disclaimer, and claims 3, 4, 6-8, 15 and 18 are amended herein. Upon entry of this amendment, claims 3, 4, 6-8, 15 and 18 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

Claims 1-20 are rejected under 35 U.S.C. 101 because this claim [sic] reads on the organism per se which is found in nature and thus, is unpatentable to applicant. (Office action page 2)

The rejection is moot for claims 1, 2, 5, 9-14, 16, 17, 19 and 20, which have been canceled without prejudice or disclaimer. The rejection of the pending claims is overcome by the amendments to the claims. Specifically, claim 3 has been amended to be limited to “*Lactobacillus casei* strain FERM BP-10059 (FERM P-19443).” Applicant refers to the Examiner's comments at the bottom of page 9 to top of page 10 of the Office action regarding “specific strain *Lactobacillus casei* FERM BP-10059.” All of the pending claims are now ultimately dependent from claim 3.

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Claims 1, 2, 4-8 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. (Office action page 3)

The Examiner notes the limitations on the *L. casei* species in claims 1 and 2, but states that “the specification only provides guidance for one specific strain designated as FERM BP-10059 (FERM P-19443).”

The rejection is moot for claims 1, 2, 5, 11-14, 16, 17, 19 and 20, which have been canceled without prejudice or disclaimer. The rejection of the pending claims is overcome by the amendments to the claims. As discussed above, claim 3 has been amended to only recite the specific strain FERM BP-10059 (FERM P-19443), and the other pending claims are all ultimately dependent from claim 3.

Claims 3, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. (Office action page 4)

The Examiner questions whether the deposit of FERM BP-10059 (FERM P-19443) meets all of the requirements of 37 CFR 1.801-1.809.

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Applicant notes that the material of FERM BP-10059 was already accepted for deposit by an International Depositary Authority (IDA) under the Budapest treaty before the filing of the present application, and that the requirements of 35 U.S.C. 112, first paragraph, are therefore met.

Applicant notes, however, that the specification did not state two of the items in 37 CFR 1.809(d): (2) The date of the deposit and (4) The name and address of the depository. Applicant therefore here amends the specification (at page 9, line 15) to include items (2) and (4) for the deposit of FERM BP-10059. The Viability Statement and Certificate in the Case of an Original Deposit for this deposit are attached to the present Amendment, for the Examiner's reference.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.
(Office action page 6)

The Examiner states that the recitation of “A *Lactobacillus casei* **species**” is confusing. This portion of the rejection is overcome by the amendments to the claims, which have been amended to refer to FERM BP-10059 as a *Lactobacillus casei* **strain**.

The Examiner refers to the conditional clauses in claim 1, and notes, for example, that limitations (2) and (3) do not specify the media, conditions, and *E. coli* strain used. This portion of the rejection is moot in view of the cancellation of claim 1 without prejudice or disclaimer.

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The Examiner states that in claim 2, it is uncertain what constitutes “widely-used antibiotics.” This rejection is moot in view of the cancellation of claim 2 without prejudice or disclaimer.

The Examiner states that in claims 4-6 and 11-14, the recitation of “as a primary active ingredient” is unclear. This portion of the rejection is overcome by the amendments to the claims, which have deleted this recitation.

The Examiner states that claims 7-9 and 15-20 are indefinite in the recitation of the process step “is applied ...” in the composition claim. This portion of the rejection is overcome by the amendments to the claims. Claims 7, 8, 15 and 18 have been rewritten as method claims. Support for this amendment may be found in the original claims, and, for example, in Example 16, beginning on page 89 of the specification.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hata et al. (U.S. Patent No. 4,314,995).
(Office action page 7).

The Examiner cites Hata et al. for disclosing “a *Lactobacillus casei* strain which appears to be identical to the presently claimed strain ... since it similarly is resistant to bile and produces an antibiotic.”

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Reconsideration of the rejection is respectfully requested in view of the amendments to the claims. As discussed above, claim 3 is now limited to “*Lactobacillus casei* strain FERM BP-10059 (FERM P-19443)” and the other claims are dependent from claim 3.

Hata et al. discloses pharmaceutical lactobacillus preparations, and discloses “single or plural strains of *Lactobacillus* having special characteristics” Five specific strains are recited in the reference: F.R.I. Nos: 1946, 2779, 2780, 2781 and 2782. It is not completely clear from Hata et al. how these strains were obtained.

Hata et al. does not appear to identify the obtained stains as *L. casei*. Applicant submits that there is no basis for the assumption that any of the five strains in Hata et al. is identical to FERM BP-10059 (FERM P-19443), to which the present claims are limited.

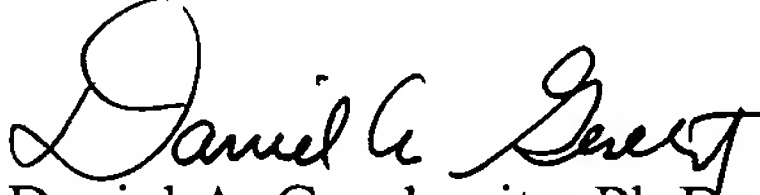
If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants’ undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

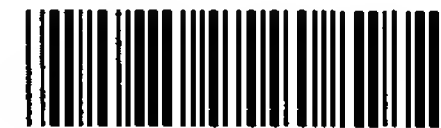
Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP


Daniel A. Geselowitz, Ph.D.
Agent for Applicants
Reg. No. 42,573

DAG/xl

Atty. Docket No. 060076
Suite 400
1420 K Street, N.W.
Washington, D.C. 20005
(202) 659-2930

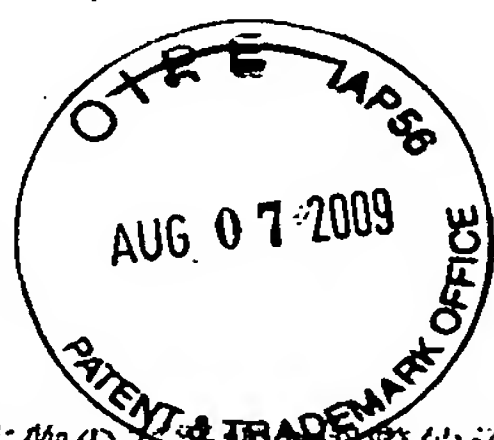


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PATENT & TRADEMARK OFFICE

Enclosures: Receipt in the Case of an Original Deposit (FERM BP-10059), with English Translation
Viability Statement (FERM BP-10059), with English Translation

H:\060\060076\Amendment in re OA of 05-07-09



(特許手続上の微生物の寄託の国際的承認
に関するブタベスト条約)

下記国際寄託当局によって規則7.1に従い
発行する。

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the INTERNATIONAL
DEPOSITARY AUTHORITY identified at the bottom of this page.

原寄託についての受託証

氏名 (名称)

寄託者

ビーエッチ,ビーエッチ,カンパニー,リミテッド
代表者 秦 忠世 殿

あて名

〒
ポストオフィス,ボックス,N7111 ナッソー,パハマ

I. 微生物の表示	
託者が付した識別のための表示 BHPH-SL-C	(受託番号) FERM BP-10059
II. 科学的性質及び分類学上の位置	
I欄の微生物には、次の事項を記載した文章が添付されていた。 <input checked="" type="checkbox"/> 科学的性質 <input checked="" type="checkbox"/> 分類学上の位置	
III. 原寄託申請の受託	
本国際寄託当局は、 年 月 日に受領したI欄の微生物を受託する。	
IV. 移管申請の受託	
本国際寄託当局は、平成 15 年 7 月 22 日(国内受託日)に受託したI欄の微生物を受託する。 (平成 15 年 7 月 22 日に寄託されたFERM P- 19443 より移管)	
V. 国際寄託当局	
独立行政法人産業技術総合研究所 特許生物寄託センター	
名称	International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology センター長 山岡 正和 Dr.Masakazu Yamaoka, Director
あて名	日本国 茨城県つくば市東1丁目1番地1 中央第6 (郵便番号305-8566) AIST Tsukuba Central 6, 1-1, Higashi 1-chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan

平成 16 年 (04) 7 月 7 日

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY
AUTHORITY identified at the bottom of this page.

Name : BHPH Company Limited (President: Tadayo HATA)
Address : Post Office Box N7117, Nassau, Commonwealth of Bahamas

1. Microorganisms	
(Reference number of an depositor) BHPH-SL-C	(Deposit number) FERM BP-10059
2. Scientific property and classification	
The following documents were attached with microorganisms of column 1. 1. <input checked="" type="checkbox"/> Scientific property <input checked="" type="checkbox"/> Classification	
3. Receipt and deposit	
The above-mentioned INTERNATIONAL DEPOSITARY AUTHORITY has received the microorganisms of column 1 on (date of an original deposit) and recognizes the deposit.	
4. Receipt of an request for a transfer	
The above-mentioned INTERNATIONAL DEPOSITARY AUTHORITY has received the microorganisms of column 1 on July 22, 2003 (date of a domestic deposit). (transferred from P-19443 deposited on July 22, 2003)	
5. International Depositary Authority	
Dr. Masakazu Yamaoka, Director International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology AIST Tsukuba Central 6, 1-1, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305-8566, JAPAN	

July 7, 2004

「特許手続上の微生物の寄託等の国際的承認
に関するブダペスト条約」

下記国際寄託当局によって規則7.1に従い
発行される。


BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the INTERNATIONAL
DEPOSITARY AUTHORITY identified at the bottom of this page.

生存に関する証明書

氏名(名称) ビーエッチ,ビーエッチ,カンパニー,リミテッド
代表者 秦 忠世 殿

寄託者 あて名 〒
ポストオフィス,ボックス,N7111 ナッソー,バハマ

1. 寄託者	2. 微生物の表示
氏名(名称) ビーエッチ,ビーエッチ,カンパニー,リミテッド 代表者 秦 忠世 あて名 〒 ポストオフィス,ボックス,N7111 ナッソー,バハマ	受託番号: FERM BP- 10059 受託の日: 平成 15 年 7 月 22 日
3. 生存試験の結果	
2欄の微生物の生存について平成 16 年 4 月 16 日に試験を実施した結果、当該微生物は、 <input checked="" type="checkbox"/> 生存していた。 <input type="checkbox"/> 生存していなかった。	
4. 生存試験に際して使用した条件(結果が否定的である場合のみ)	
<input type="checkbox"/> 微生物条件記録書 1通	
5. 寄託当局	
独立行政法人産業技術総合研究所 特許生物寄託センター 名称 International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology センター長 山岡 正和 Dr. Masakazu Yamaoka ; Director  あて名 日本国 茨城県つくば市東1丁目1番地1 中央第6(郵便番号305-8566) AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan	

平成 16 年 (2004) 4 月 16 日

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY
AUTHORITY identified on the following.

Name : BHPH Company Limited (President: Tadayo HATA)
Address : Post Office Box N7117, Nassau, Commonwealth of Bahamas

1. Depositor
Name : BHPH Company Limited (President: Tadayo HATA) Address : Post Office Box N7117, Nassau, Commonwealth of Bahamas
2. Microorganisms
Deposit number : FERM BP-10059 Deposit date : July 22, 2003
3. Results of existence examination
As a result of existence examination of a microorganism of column 2, performed on April 16, 2004, the microorganism was <input checked="" type="checkbox"/> existing. <input type="checkbox"/> not existing.
4. Conditions applied for the existence examination, in case of only a negative result
<input type="checkbox"/> Duplication of a record of microorganism conditions ... one sheet
5. International Depositary Authority
Dr. Masakazu Yamaoka, Director International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology AIST Tsukuba Central 6, 1-1, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305-8566, JAPAN <div style="text-align: right;">April 16, 2004</div>